Proposed Decision Memo for Lung Volume Reduction Surgery (CAG-00115R2)

Decision Summary

Through this decision memorandum, CMS proposes to modify CMS Publication 100-3 Section 240.1.A.2.c to state:

CMS has determined that LVRS performed on or after xx/xx/xx (18 months from the effective date of this decision) is reasonable and necessary only when performed at facilities that are certified by the Joint Commission on Accreditation of Healthcare Organizations Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the October 25, 2004 Disease Specific Care Certification Program packet) or when performed at facilities that are Medicare-approved for lung or heartlung transplantation. Surgeries performed between January 1, 2004 and xx/xx/xx are reasonable and necessary when performed at facilities that were approved by the National Heart Lung and Blood Institute (NHLBI) to participate in the National Emphysema Treatment Trial (NETT), facilities that are Medicare approved for lung or heart-lung transplantation, or facilities that have been certified by the Joint Commission.

CMS proposes that lung or heart-lung transplant facilities have Medicare approved transplant status at the time the LVRS is performed. CMS proposes that facilities that seek to satisfy the facility requirement through Joint Commission certification be certified at the time the LVRS is performed. NETT facilities that are not Medicare approved for lung or heart-lung transplantation are encouraged to become Joint Commission-certified or a Medicare approved transplant center within 18 months after the effective date of this decision in order to continue to receive Medicare payment for LVRS after that date. A list of approved facilities will be continuously updated and available on the CMS web site at http://www.cms.hhs.gov/coverage/lvrsfacility.pdf.

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Proposed Decision Memo

TO: Administrative File: CAG 00115R2

Lung Volume Reduction Surgery

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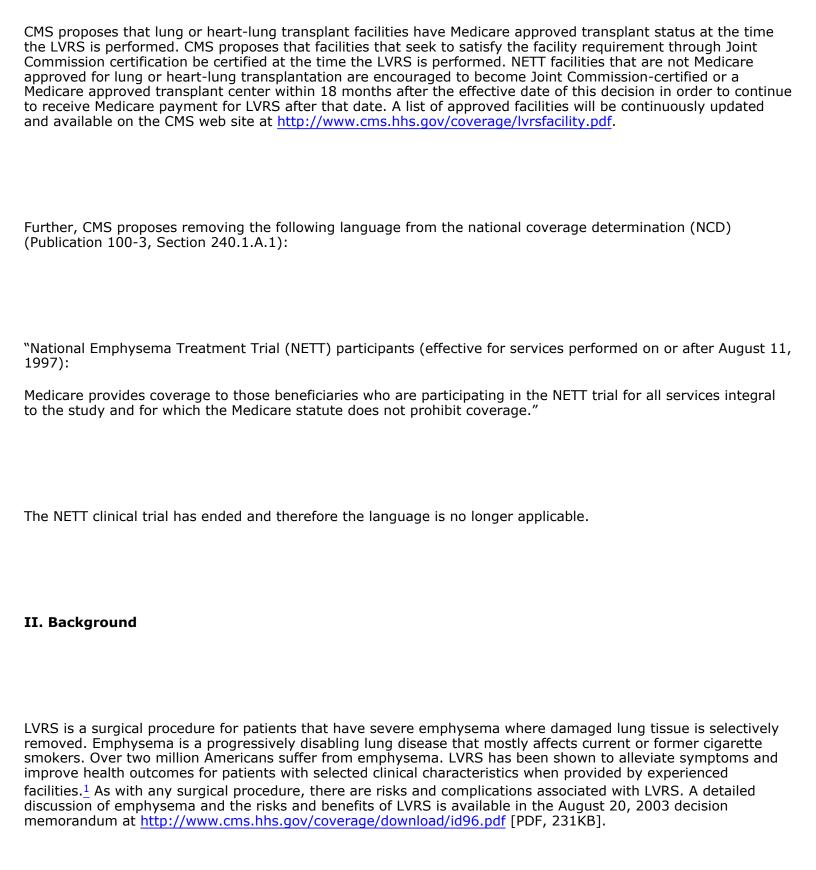
SUBJECT: Proposed Coverage Decision Memorandum for Lung Volume Reduction Surgery

DATE: August 18, 2005

I. Proposed Decision

Through this decision memorandum, CMS proposes to modify CMS Publication 100-3 Section 240.1.A.2.c to state:

CMS has determined that LVRS performed on or after xx/xx/xx (18 months from the effective date of this decision) is reasonable and necessary only when performed at facilities that are certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the October 25, 2004 Disease Specific Care Certification Program packet) or when performed at facilities that are Medicare-approved for lung or heartlung transplantation. Surgeries performed between January 1, 2004 and xx/xx/xx are reasonable and necessary when performed at facilities that were approved by the National Heart Lung and Blood Institute (NHLBI) to participate in the National Emphysema Treatment Trial (NETT), facilities that are Medicare approved for lung or heart- lung transplantation, or facilities that have been certified by the Joint Commission.



On February 17, 2005 the Centers for Medicare and Medicaid Services (CMS) formally received a request submitted by the Joint Commission to allow hospitals certified through its disease- specific care certification program for LVRS to be Medicare-approved LVRS facilities. The agency then began the review of this request for reconsideration of the previous national coverage determination (NCD) for LVRS. The purpose of this reconsideration is to evaluate the LVRS program requirements developed by the Joint Commission in order to determine whether these criteria are consistent with the current Medicare requirements.

CMS is only reviewing the process for determining if LVRS facility standards are met. We are not reviewing any other standards in the LVRS NCD. All other requirements of the current Medicare NCD for LVRS remain applicable. Also, while this reconsideration proposes Joint Commission certification as an alternative mechanism to assess that facilities meet staff and facility requirements under Medicare, if requested by other third-party entities, CMS will evaluate additional programs designed to evaluate facilities wishing to furnish LVRS services.

III. History of Medicare Coverage

Prior to December 1995, Medicare did not have a national coverage policy regarding LVRS and coverage for the procedure was overseen by Medicare contractors. Due to concerns for patient safety and inadequate medical evidence supporting the procedure, CMS issued a national policy in December 1995 non-covering LVRS.

In 1996, CMS and the National Heart, Lung and Blood Institute (NHLBI) agreed to jointly sponsor the National Emphysema Treatment Trial (NETT), a multi-centered, controlled clinical trial to compare LVRS with medical management in the treatment of severe emphysema. Between 1996 and 2003 CMS only covered LVRS when it was performed on patients enrolled in the NETT.

The published results from the NETT served as the basis of the August 2003 Medicare decision memorandum mentioned above to broaden LVRS coverage in order to include provision outside of the trial for patients with particular clinical indications. In addition to carefully outlining the patient population, this decision allowed LVRS only to be performed in facilities that were Medicare-approved for lung transplants or had been approved as NETT centers. Expanded coverage for LVRS became effective on January 1, 2004.

IV. Timeline of Recent Activities

August 20, 2003

CMS issues the Decision Memorandum announcing the intention of CMS to cover LVRS for specific clinical indications and the intention to consider allowing a third party program to certify Medicare-approved LVRS facilities.

January 1, 2004	CMS coverage of LVRS becomes effective.
February 17, 2005	CMS opens a reconsideration for LVRS to review third party certification standards for facilities performing this procedure.
March 17, 2005	Initial 30-day public comment period closes.

V. FDA Status

LVRS is a surgical procedure that does not require FDA approval.

VI. Methods

In this memorandum, CMS compares the Joint Commission program requirements to the existing Medicare LVRS facility requirements that served as the basis for approving NETT centers and lung transplant centers in January 2004. Our examination consisted of:

- Reviewing the process used by the Joint Commission to develop their standards; and
- Comparing the Joint Commission standards with the general standards for LVRS facilities established by CMS and whether the LVRS-specific certification criteria proposed by the Joint Commission are at least equivalent to the CMS standards and therefore likely to identify facilities that furnish LVRS in a reasonable and necessary manner.

Further, CMS explains why the designation of currently approved NETT facilities will terminate in the future due to the cessation of oversight provided by NIH. We propose an alternative method for those hospitals to become certified so that they may continue to receive Medicare payment for covered LVRS procedures.

VII. Assessment 1. Assessment questions In this assessment, CMS seeks to address the following questions: • Are the Joint Commission standards at least equivalent to the CMS standards used to select NETT and transplant centers in the January 2004 decision? • Should facilities selected as NETT centers continue to be approved as LVRS facilities? • What impact will the proposed transplant regulation have on LVRS approved facilities²? 2. Current CMS requirements for LVRS facilities In the August 2003 decision memorandum, by selecting the sites that had been approved by NHLBI to participate in the NETT as Medicare-approved programs, CMS implicitly adopted the facility standards that had been utilized by NHLBI to identify facilities qualified to participate in the trial.³ These requirements included, among others, that each facility had assembled an integrated team expert in pulmonary medicine, had a close working relationship with a lung or heart-lung transplantation center, and had the ability to provide relevant patient outcome data. CMS adopted the NHLBI-derived standards by initially restricting approved facilities to those that participated in the NETT in addition to Medicare-approved transplant centers, which were presumed to have met the above criteria. The NHLBI standards are explicitly stated below:

The facility must ensure that all individuals who provide services and/or supervise services in the LVRS

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program are qualified to provide or supervise such services.

- The facility must identify a multidisciplinary LVRS team and describe the responsibilities of each member
 of the team. The team must be composed of individuals with the appropriate qualifications, training and
 experience in the relevant areas of pulmonary medicine, pulmonary rehabilitation, thoracic surgery, critical
 care anesthesia, and pulmonary radiological assessment.
- The primary surgeon participating in the program must have experience performing LVRS procedures.
- The pulmonary specialist(s) must have training and clinical expertise in managing and treating end-stage emphysema patients, have a firm understanding of pulmonary medicine and pulmonary rehabilitation, and have experience in managing patients undergoing LVRS.
- The facility must demonstrate a close working relationship with or be a Medicare lung or heart-lung transplantation center to ensure that patients are adequately evaluated for both LVRS and lung transplant prior to the surgical procedure.
- The facility must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, infectious disease control, pathology, radiology, physical therapy and blood banking as related to the provision of LVRS.
- The facility must establish and implement written policies to address and document adverse events that occur during the management of an LVRS patient.
- The facility must have a written informed consent process that informs each patient of: 1) the evaluation process; 2) the surgical procedure; 3) alternative treatments; 4) national and center-specific rates for potential surgical risks, hospital lengths of stays, 30-day mortality and other relevant outcome measures; 5) risk factors that could affect the success of the surgery; 6) the patient's right to refuse the intervention.

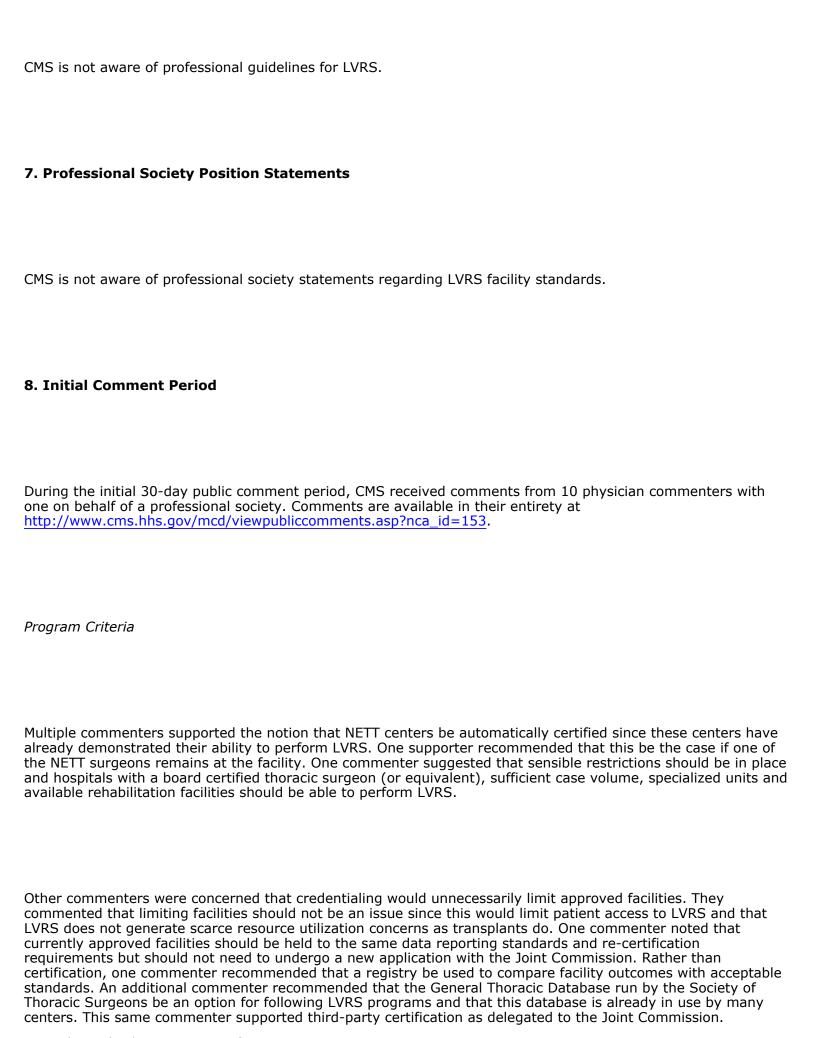
In addition, NHLBI required that NETT facilities had the capacity to collect, analyze and provide pre-operative, post-operative and follow-up data. Accordingly, the facility's quality improvement program would utilize objective measures to periodically evaluate the LVRS program's performance with regard to LVRS services and outcomes. Services and outcomes could include, but were not limited to patient selection criteria, consent practices, length of stay, surgical and medical complications and early (30-day) or late (90-day) mortality rates. LVRS programs maintain these and other relevant data (e.g., number of procedures performed by individual practitioners). In sum, we expected that each LVRS program would take actions resulting in performance improvements and would track performance to ensure that improvements were sustained.

In order to provide adequate access to LVRS while preserving a high standard of care, CMS also concluded that the NETT results were likely to be applicable to lung transplant centers for which CMS had already developed criteria for approval under the Medicare program. We believed that the kind of integrated team assembled at the NETT sites with expertise in pulmonary medicine – especially as it related to end-stage emphysema, pulmonary rehabilitation, thoracic surgery, critical care anesthesia, quality of life and dyspnea measurements, and pulmonary radiological assessment – would be present or could be readily established at Medicare-approved lung transplant facilities. We also understood that experienced lung and heart-lung transplant surgeons could perform LVRS with beneficial results given the overlap of skills required for both surgical procedures.

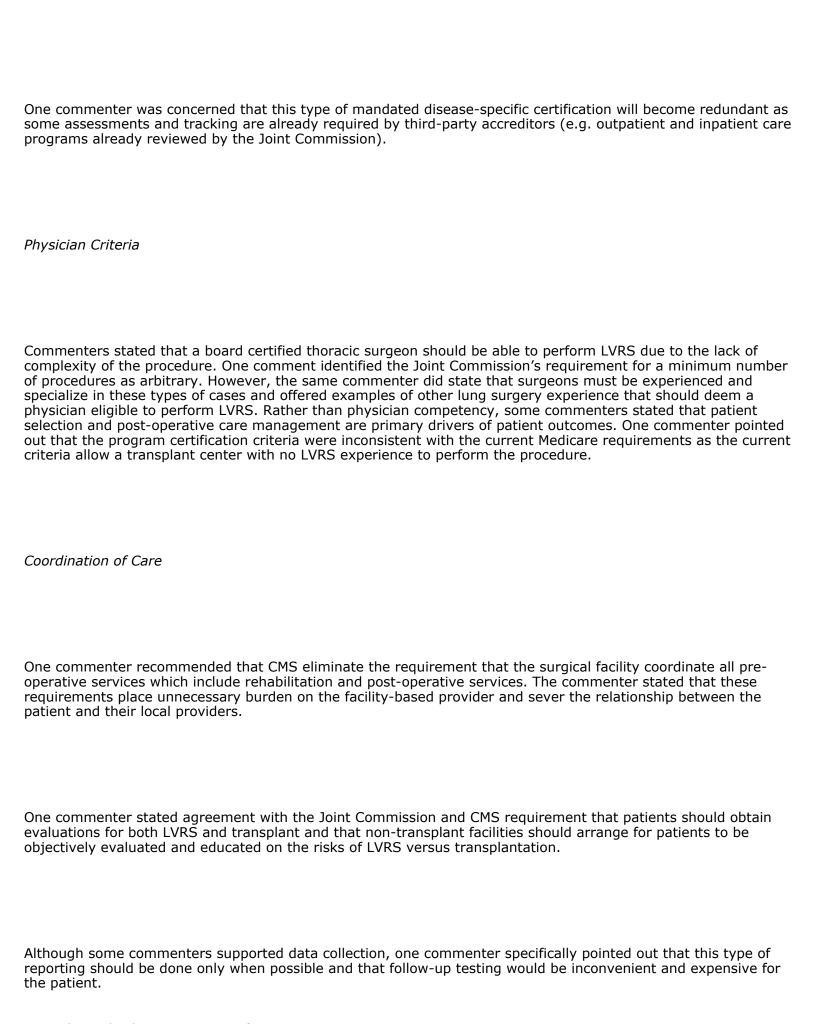
3. Joint Commission: Standard development

The proposal submitted to CMS for LVRS certification was developed within the framework common to all the disease-specific certification programs offered by the Joint Commission. It contains a core set of standards and the corresponding elements of performance for each standard applicable to the individual condition of interest, for example stroke or asthma. Elements of performance are measurable characteristics used to evaluate compliance with standards and thus inform the Joint Commission's review procedures. Elements of performance specifically required for certification of LVRS facilities were incorporated into this framework.⁴

In order to develop the LVRS-specific elements of performance in the proposed certification program, the Joint Commission assembled a task force composed of physicians representing the Society of Thoracic Surgeons, the American College of Chest Physicians, and other experts including cardiothoracic surgeons. These selected experts provided their view on the characteristics critical to the structure and operation of a program capable of providing appropriate services centered on this procedure as well as on patient inclusion/exclusion criteria.
To obtain public input, the Joint Commission posted the proposed LVRS requirements on its web site and solicited comments directly from over 60,000 individuals enrolled on the Joint Commission list serve. The comments received were incorporated where appropriate. The standards were reviewed again by the expert panel before a final LVRS certification program proposal was submitted to CMS. 5
The proposed LVRS certification program involves a two-year award cycle with an off-site and an on-site evaluation in the first year and an off-site intra-cycle evaluation during the second year. Certification is limited to hospital-based programs. Review of pre- and post-surgery rehabilitation services is to be conducted as part of the evaluation of the hospital program's ability to provide or coordinate all required services. The proposed standards and elements of performance developed by the Joint Commission for LVRS certification and printed in the Octobe 25, 2004 Disease Specific Care Certification Program packet are listed in appendix A.
4. External technology assessments
No external technology assessment was commissioned for this review.
5. MCAC
The Medicare Coverage Advisory Committee was not convened to review this issue.
6. Evidence-based guidelines



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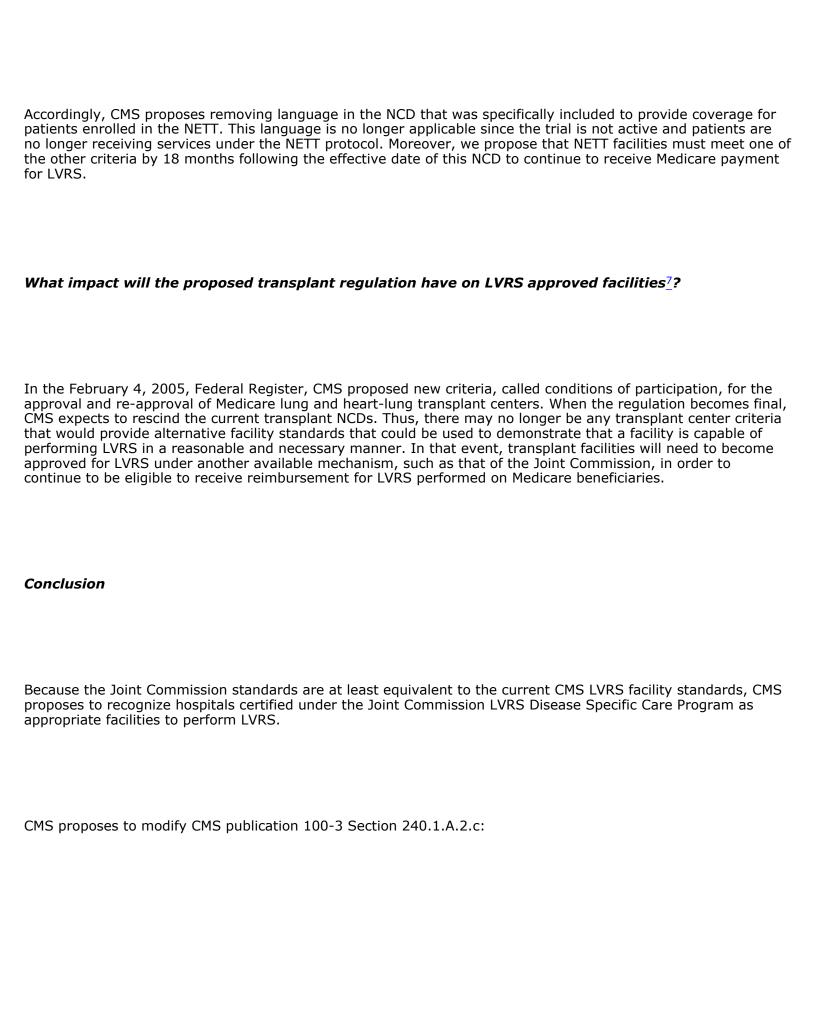


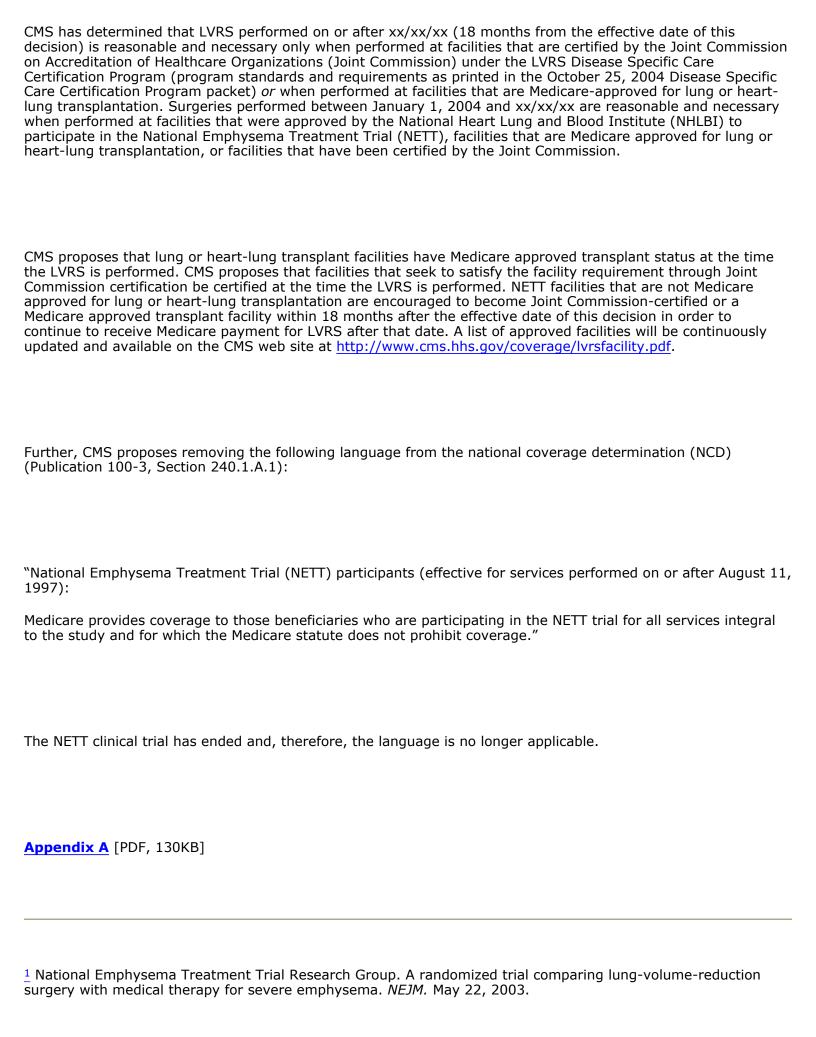
Clinical Indications
One commenter discussed the subjective nature of the inclusion and exclusion criteria stating that these criteria are impossible to audit and that such specific criteria run counter to relying on skilled practitioners to make determinations. This commenter recommended that patient outcomes be the basis of certification rather than specific clinical criteria.
One commenter pointed out that the high-risk patient population identified in the 2002 New England Journal article was not specifically excluded in the Joint Commission standards.
VIII. CMS Analysis
National coverage determinations (NCDs) are determinations made by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1862(I)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).
We previously concluded that LVRS was reasonable and necessary for certain patients meeting specific criteria if performed in certain qualified facilities. We have been asked to modify this NCD to permit coverage in facilities that meet alternative standards. Except as noted below, all other aspects of the existing NCD remain unchanged.
Are the Joint Commission standards at least equivalent to the CMS standards used to select NETT and transplant centers in the January 2004 decision?





Since the formal relationship no longer exists, CMS can no longer be assured that the NETT centers are maintaining the standards that were once approved by NHLBI for participation in the clinical trial.





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² Federal Register. 6140. Vol. 70. No. 23. February 4, 2005.
3 NHLBI: Request for proposals for the National Emphysema Treatment Trial. <i>Commerce Business Daily</i> . June 3, 1996. The Executive Steering Committee (ESC) for the study assembled a panel of experts and reviewed all submitted RFPs in September 1996. Ultimately, 18 centers met the threshold requirements set out by the ESC.
4 Joint Commission: Letter to CMS. March 31, 2004.
5 Letter to CMS from the requestor. January 25, 2005.
6 As mentioned above, the process utilized by Joint Commission to develop and review the LVRS-specific standards and elements of performance has been based on expert consensus and also open for review to a reasonably broad audience of health care organizations and individuals.
7 Federal Register. 6140. Vol. 70. No. 23. February 4, 2005.
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